Exhibit B
to Declaration of Christopher M. Denig, Dated August 9, 2018

[Filed Under Seal]

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, THE CITY OF CHICAGO AND THE CITY OF NEW YORK *ex rel* OMNI HEALTHCARE INC.

VERSUS

AMERISOURCEBERGEN, AMERISOURCEBERGEN SPECIALTY GROUP, ION SOLUTIONS, ONCOLOGY SUPPLY, MCKESSON CORPORATION, ONCOLOGY THERAPUETICS NETWORK, AND U.S. ONCOLOGY.

CIVIL ACTION
NO. CV 12-1178

JUDGE:
MATSUMOTO/ MAG. BLOOM

FILED *IN CAMERA* AND UNDER SEAL

DO NOT ENTER INTO PACER

FIRST AMENDED QUI TAM COMPLAINT FOR DAMAGES

NOW INTO COURT, through under signed counsel, comes Relator, Omni Healthcare Inc., in the name of and on behalf of the United States of America, the States of California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, the City of Chicago, and the City of New York, by its attorneys, Vezina and Gattuso, pursuant to 31 U.S.C.

§3730(b)(1) and the False Claims Acts of the States and Cities, as defined and listed herein, and alleges as follows:

Introduction

1. This action arises under 31 U.S.C. § 3729 *et* seq., also known as the False Claims Act ("FCA"), as well as the False Claims Acts of the States and Cities (collectively "State FCAs"), and common law, to recover treble damages and civil penalties on behalf of the United States of America, the States, and Cities, arising out of Defendants violations of the FCA and State FCAs as well as under common law theories of payment by mistake and unjust enrichment.

2. As more fully alleged herein, this action arises out of a scheme or schemes to defraud the United States of America, the fifty States, and the District of Columbia, and the named Cities herein, perpetrated by the Defendants, commencing on or before 2004 and continuing to and including the date of filing herein as an ongoing scheme. The Defendants made and/or caused to be made to the United States, the fifty State governments, the District of Columbia, and the named Cities herein false claims for payment for prescription drugs covered by Medicare, State Medicaid Programs, the Department of Veterans Affairs, the Public Health Services and other federal, state, and city purchasers of prescription drugs. Claims were false and fraudulent because the drugs, which were distributed by Defendants to providers throughout the country, to patients in the United States of America were adulterated by Defendants. The false claims arose out of a chronic, serious and knowing scheme which resulted in the deficiency in the handling and adulteration of the products in Defendants' possession in violation of the laws and regulations designed to ensure the fitness of drug products

where used, including the Federal Food, Drug and Cosmetics Act, 31 USC §§ 301 *et seq.*, and the Code of Federal Regulations, Title 21.

3. Defendants further created a scheme to defraud the United States of America and the fifty States, the District of Columbia, and the Cities mentioned above by creating a program under which physicians are given a financial incentive (i.e., discount and free services) to buy their drugs in newly re-manufactured and re-packaged pre-filled syringes from Defendants as created by Defendants instead of purchasing them as they were packaged for distribution and sale by the manufacturer.

4. These acts constitute violations of the Federal False Claims Act, 31 USC § 29 *et seq.* ("FCA"), and numerous equivalent state and city statutes. The FCA provides, *inter alia*, that any person who knowingly presents and/or causes to be presented to the United States a false or fraudulent claim for payment is liable for a civil penalty of up to $11,000.00 for each claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. §3729. The FCA also allows any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. 31 U.S.C. §3730.

Jurisdiction and Venue

5. Under §3732 of the FCA, this Court has exclusive jurisdiction over the actions brought under the FCA and concurrent jurisdiction over state claims arising from the transactions giving rise to the claims under the FCA. Furthermore, jurisdiction over this action is conferred on this Court by 28 U.S.C. §1331 because this civil action arises under the laws of the United States.

6. This Court has supplemental jurisdiction over all other claims set forth in this Complaint because these claims are so related to the claims arising under the federal False Claims Act that they form part of the same case or controversy. 28 U.S.C. §1367.

7. Venue is proper in this district pursuant to §3732(a) of the Act, which provides that any action under §3730 may be brought in any judicial district in which the Defendant or in the case of multiple Defendants, any one Defendant, can be found, resides, transacts business, or in which any act proscribed by §3729 occurred. Acts that are the subject of this action occurred in the State of New York, within this judicial district, as well as nationwide. At all times material thereto, Defendants regularly conducted substantial business within the State of New York, maintained permanent employees in the State of New York, and made, and is making, significant sales and claims for reimbursement within the State of New York, within this judicial district. Additionally, venue is proper in this district pursuant to 28 U.S.C. §1391(b)(1)-(2).

Filing Under Seal

8. Under the Act, as well as State and City FCAs, this Complaint is to be filed *in camera* and remain under seal for a period of at least sixty (60) days and shall not be served on Defendants until the Court so orders.

9. As required by the FCA, Relator voluntarily submitted prior to the filing of this Complaint a confidential written disclosure statement (subject to the attorney client privilege) to the United States Government, containing materials, evidence, and information in their possession pertaining to the allegations contained in this Complaint. Similarly, Relator voluntarily submitted a confidential written disclosure statement and this Complaint to the States and Cities whose FCAs form the bases of this action.

PARTIES

The Relator

10. Relator, Omni Healthcare, Inc., is a professional medical company primarily based in Brevard County, Florida. It serves patients in the practice of hematology/oncology throughout central Florida. Its practices through physicians in central Florida and specializes in the field of internal medicine with a subspecialty in hematology and oncology. Relator through its principals regularly treats cancer patients on both an inpatient and outpatient basis and regularly purchases drugs from various distributors and wholesalers in order to treat its patients for both the underlying disease condition, as well as for the other conditions associated with cancer and attendant side effects

11. Relator is an original source of the facts and information hereinafter set forth concerning the activities of the Defendants relative to the manufacture, adulteration, promotion, and sales of the pre-filled syringes being created, adulterated, manufactured, promoted, and sold by Defendants, which are then improperly being billed to Medicare, the States' Medicaid Programs, and other federal, state, and city reimbursement programs. The facts averred herein are based upon Relator's personal observation and documents and information in his possession, which were acquired by him in connection with his work as a treating oncologist, treating patients with cancer using Defendants' drugs.

12. Relator seeks to recover damages and civil penalties in the name of the United States and the States for the violations alleged herein.

Defendants

13. Defendant AmerisourceBergen Drug Corporation ("ABDC") is the world's largest pharmaceutical services company with its headquarters in Valley Forge, PA, and services

the United States, Canada, and selected global markets and has locations throughout the United States, Puerto Rico, Canada, and UK, and does business throughout the fifty States and the District of Columbia through its agents, employees, business units, and subsidiaries, including but not limited to Defendant AmerisourceBergen Specialty Group, Defendant ION Solutions, and Defendant Oncology Supply.

14. Defendant ABDC is publicly traded on the New York Stock Exchange as NYSE:ABC.

15. Defendant ABDC, including all of its business units and subsidiaries, handles about 20% of all of the pharmaceuticals sold and distributed in the United States.

16. Defendant ABDC is a global wholesale supplier of pharmaceuticals, medical-surgical supplies, and specialty healthcare products, and also provides information management and consulting services, including but not limited to consultant pharmacist services.

17. Defendant AmerisourceBergen Specialty Group ("ABSG") is a separate legal entity and subsidiary of ABDC, headquartered in Frisco, Texas, and is considered an operating segment of the parent company, serving as the specialty pharmaceutical arm of ABDC. ABSG provides pharmaceutical distribution and other services primarily to physicians who specialize in a variety of diseased states, especially oncology, and also distributes drug products and provides third party logistics and other services for biotechnology and other pharmaceutical manufacturers.

18. Defendant ION Solutions ("ION") is one of the sister companies which make up ABSG and is also located in Frisco, Texas. ION represents more than ½ of the community based oncology market in the United States. It provides reimbursement solutions, patient adherence and compliance programs, health outcomes, research, product analytics, and specialty pharmacy services.

19. Defendant Oncology Supply ("OS") serves as ION's exclusive distribution partner and is part of the ABSG family and is also located in Frisco, Texas. OS serves as the United States largest distributor of oncology products to private practice oncologists. Its pharmacy is located in Dothan, Alabama.

20. Defendant ABDC and its subsidiaries and divisions are collectively referenced herein as "ABDC Defendants."

21. Defendant McKesson Corporation ("McKesson") is the largest pharmaceutical distributor in North America, distributing one third of the medicines used in North America, supplying more than 40,000 U.S. health care locations from Wal-Mart to the Department of Veterans Affairs to community pharmacies.

22. Defendant McKesson is headquartered in San Francisco, California and is publicly traded on the New York Stock Exchange under the symbol "MCK."

23. Defendant McKesson is ranked 15th on the FORTUNE 500 with more than $112.1 billion in annual revenue. It boasts as its customers 200,000 physicians, 26,000 retail pharmacies, 10,000 long-term care sites, 5,000 hospitals, 2,000 medical-surgical manufacturers, 750 homecare agencies, 600 health care payors, 450 pharmaceutical manufacturers.

24. Defendant Oncology Therapeutic Network ("OTN") was purchased by McKesson in October 2007.

25. Defendant OTN is a specialty division of McKesson, called a "McKesson Specialty Company" and is based in South San Francisco, California.

26. Defendant US Oncology was purchased by McKesson in December 2010.

27. Defendant US Oncology is a division of McKesson Specialty Health.

28. Defendant US Oncology is the nation's leading integrated oncology company uniting the largest community based cancer treatment and research network in the United States.

29. Defendant US Oncology is headquartered in The Woodlands, Texas.

30. Defendant McKesson with its subsidiaries and divisions are collectively referenced herein as "McKesson Defendants."

31. Collectively, ABDC with each of its subsidiaries and divisions and McKesson with each of its subsidiaries and divisions are referenced herein as "Defendant Manufacturer/Distributors."

32. Beginning in 2001, Defendant Manufacturer/Distributors have taken certain injectable oncology drugs, including but not limited to, Aranesp, Neupogen, Procrit, Aloxi, Anzemet, Kytril (both brand and generic) and Taxotere, which come already packaged by the original manufacturer in single dose and/or multi-dose vials and remove and pool the oncology liquid from those vials to be placed into Defendant Manufacturer/Distributors' own pre-filled syringes which are then distributed to the provider/physicians for patient treatment. It is this conduct, the removal and pooling of Oncology Drugs into Defendant Manufacturer/Distributors' own pre-filled syringes through their own Pre-filled Syringe Program, which forms the basis of the Complaint.

Affected Government Programs

33. Medicaid is the nation's medical assistance program for the needy, the medically-needy aged, blind, and disabled in families with dependent children. See 42 USC §§ 1396-1396v. Medicaid is largely administered by the States and funded by a combination of federal and state funds. Approximately 57% of Medicaid funding is provided by the Federal Government on a national basis. Among other forms of medical assistance, the

Medicaid programs cover outpatient prescription drugs. See 42 USC §§ 1397a(10)(A) and 1396d(a)(12).

34. Medicare is the nation's health program for persons over 65 years of age and the disabled. Medicare is funded by the Federal Government. Medicare Part B has long covered outpatient prescription drugs that are provided through a patient "incident to" a physician's services, including injectable medications, and drugs that are required for the effect use of durable medical equipment. See 42 USC § 1395x(s)(2)(A). Commencing on January 1, 2006, Medicare Part D provides comprehensive outpatient prescription drug coverage for brand name and generic drugs according to National and Local Coverage Determinations. See Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173.

35. The Department of Veterans Affairs ("VA") provides medical assistance, including prescription drug coverage, to persons who have been discharged from active duty service in the military, naval, or air services.

36. The Public Health Service ("PHS") provides funding, including outpatient drug coverage, for entities such as black lung clinics, AIDS drug purchasing assistance programs, hemophilia diagnostic treatment centers, urban Indian organizations, disproportionate share hospitals, and other entities listed in § 340B(a)(4) of the Public Health Service Act.

37. The Department of Defense ("DOD") administers the TRICARE health care program for active duty and retired members of the uniformed services, their families, and survivors. TRICARE benefits include comprehensive prescription drug coverage.

38. The Food and Drug Administration ("FDA") is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs,

biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA administers *inter alia,* the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 USC §§ 301 *et seq.*

The FDA Regulatory Process to Ensure the Safety and Efficacy of Drug Products Consumed by Americans through a Combination of Approval Inspection, Enforcement, and Self-Regulation by Drug Manufacturers And Drug Distributors in the Chain of Commerce

39. The current Good Manufacturing Practices ("cGMPs") contain the minimum requirements that pharmaceutical companies must meet in manufacturing, processing, packing, and holding drugs to assure that they meet the safety, identity, strength, quality, and purity characteristics that they purport to possess. The cGMPS are codified in 21 C.F.R. Parts 210 and 211. Manufacturers demonstrate compliance with cGMPs through written documentation of procedures and practices. The cGMPs dictate, *inter alia*, standards for: personnel engaged in quality control; the design, construction and maintenance of buildings and facilities; the construction, cleaning and maintenance of equipment; the storage, inspection and testing of drug components and containers; the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage and distribution; laboratory controls including testing of drug product batches for conformity with final specifications; maintenance of records and reports and conduct of investigations; and procedures for handling of returned and salvaged product.

40. Drugs are deemed to be adulterated if they are not manufactured in compliance with the cGMPs or if they are contaminated. See 21 USC §§ 351(a)(2)(A)(B). It is a violation of

the FDCA, 21 USC § 331(a) to directly or indirectly cause adulterated drugs to be introduced or delivered for introduction into interstate commerce.

41. 21 USC §§ 355(b)(1)(D)-(B) provides that applications to the FDA for approval of new drugs ("NBAs") must include: (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug. Approval by the FDA of this drug formula and method of manufacture is required for introduction of the drug in interstate commerce and distribution for human use. 21 USC §§ 314.70 and 314.81 respectively requires manufacturers to obtain FDA approval for, or make the FDA aware of, changes in the conditions established in an approved application.

42. Major changes to drugs post FDA approval, which have substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product require advance submission of a supplement to and approval by the FDA.

43. Under the FDA guidelines, for sterile drugs, like Aranesp, Neupogen, Procrit, Aloxi, Anzemet, Kytril and Taxotere, a change in the primary packaging components for any drug product when the primary packaging components control the dose delivered to the patient, a change to a pre-filled syringe dosage form from another container system, and/or a change from a single unit dose container to a multiple dose container system, among other changes, require advance approval by the FDA before such changes are implemented.

44. By Defendant-Manufacturer-Distributors engaging in material and major changes to FDA approved drugs, they are acting as a manufacturer and creating, manufacturing, distributing, and selling drug products without FDA approval and in violation of FDA requirements.

The Anti-Kickback Statute

45. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 USC § 1328-7d ("AKS"), arose out of congressional concern that the remuneration and gifts given to those who influence health care decisions corrupts the medical decision making process and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs, congress enacted the AKS in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful…and which contribute appreciably to the cost of Medicare and the Medicaid Programs." H.R. Rep. No. 92-231, (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

46. The AKS prohibits any person or entity from knowingly or willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any state health care program or health program funded in part by the federal government. See 42 USC § 1320a-7b(b), 1320a-7b(f).

47. The AKS not only prohibits out right bribes and rebate schemes, but also prohibits any payment to a physician which has as one of its purposes inducement of the physician to write prescriptions for a particular product.

48. Compliance with the AKS is a precondition to participation as a health care provider under the federally funded health care program and the state Medicaid program.

Regulatory Framework for Injectable Vials and the Required Overfill

49. Drug injectables are often manufactured, packaged, and sold in single use (dose) and multi-use (dose) vials. The amount of drug contained in each vial and the packaging of such drug for injection are pre-approved by the FDA and part of the package label.

50. The injectable drugs at issue in this case are cancer treating drugs used by physicians for oncology patients in their offices, including but not limited to Aranesp, Neupogen, Procrit, Aloxi, Kytril (brand and generic) and Taxotere (collectively "Oncology Drugs").

51. These Oncology Drugs are manufactured by "original manufacturers" that have been submitted to and approved through the regulatory process set forth by law and regulation to produce and sell drugs in the United States.

52. Many drugs for cancer patients and for patients who are suffering from anemia, or nausea and vomiting are manufactured in single dose vials, meaning one vial per use per patient.

53. In addition, some drugs are manufactured in prefilled single dose syringes or multi-dose vials, meaning multiple injections for the same patient over a period of time, or multiple injections for multiple patients out of the same vial.

54. Each of these oncology drugs have its own unique drug codes ("NDC") which vary for each individual drug based on distribution method (vial, syringe, autoinjector) and by the dose and quantity of the drug.

55. Manufacturers and suppliers submit claims for drugs to the Medicare and Medicaid programs using the NDCs for the particular drug sold or delivered.

56. Medical providers who administer these drugs to Medicare beneficiaries and Medicaid recipients on an outpatient treatment basis, however, submit claims to Medicare and state Medicaid programs using procedure codes.

57. Examples of procedure codes for the oncology drugs at issues are: Aranesp J0881, J0882; Neupogen J0885, J0886; Procrit J1440, 1441; Aloxi J2469; and Taxotere J9170.

58. The United States Pharmacopeia ("USP") requires that injectable drug vials contain a volume overage in "slight excess" of the labeled volume fill amount in order to permit withdrawal and administration of the label fill volume amounts. See USP Reference Standards, XXXI Rockfield, MD: (2008 Chapter 1151, page 619). This "slight excess" fill volume, or overage, is commonly referred to as the "overfill." For the entire time that drugs have been on the market, the USP has recommended up to an additional .1 milliliter, or 10 percent overfill for a filled volume of up to 1 milliliter.

59. Many manufacturers however place additional overfull or excess volume in their vials in order to ensure that patients receive the proper amount from the vial and there is no shortage in the particular injection given to a particular patient.

60. The sole purpose of the overfill in a vial is to enable a medical provider to extract and administer the full labeled dose as prescribed by the physician and as approved by the FDA.

61. Manufacturers are required to document and report to the FDA the amount and purpose of such overfill and to keep such reporting current. *See* FDA Compliance for Drug Product Formulation Development 2.2.1.

62. Overfill itself is not meant to be administered to a patient and is not paid for by the doctor when purchasing the vial from the manufacturer through a distributor.

Reimbursement Framework for Injectable Vials

63. It has long been Medicare policy that services or supplies must represent an actual expense actually incurred by the physician or medical provider in order to be reimbursed by Medicare. Because physicians incur no cost for overfill, it is not reimbursable by Medicare. Specifically, the Medicare Reimbursement Policy Manual, §50.3 provides that "[t]he cost of the drug or biological for which reimbursement is sought must represent an expense to the physician," and further provides that §60.1A that "To be covered supplies, including drugs and biological, must represent an expense to the physician or legal entity billing for the services or supplies." See Medicare Reimbursement Policy Manual Chapter 15.

64. The Center for Medicare and Medicaid Services ("CMS") set the reimbursement rates for these drugs to account for waste in the vial (the difference between the amount drawn and the label amount – **not the overfill**). See Medicare Claims Processing Manual, Chapter 17, Section 40, revised July 2007: "*If after administering a dose/quantity of the drug or biological to a Medicare patient, a provider must discard the remainder of the single dose vial, the program provides payment for the amount of the drug/biological administered and the amount discarded,* ***up to the total amount of the drug/biological as indicated on the vial or package label.***"

65. Since 2005 Medicare has been reimbursing these kinds of injectable drugs under its Part B program and CMS reimburses based on the average sales price ("ASP") which represents the manufacturer of the drugs total sales divided by the total number of units

sold during the particular quarter. See 42 USC § 1395w-3a(c)(1)(A)-(b). Manufacturers are required to "deduct the price concessions" from the numerator of this mathematical equation, which includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, charge backs, and rebates. *Id.* § 1395w-3a(c)(a); see also 42 CFR § 414.804(a)(2)(i). Overfill is not explicitly mentioned in the statute as a type of price concession. Acting in conjunction with OIG, the Secretary of HHS, which houses CMS, has authority to identify "other price concessions" beyond those already enumerated in the statute, but it has not done so with respect to overfill.

66. The exclusion of overfill as a price concession is, in fact, a conscious decision by CMS. In November 2010, the agency, consistent with its rule making authority, promulgated its final rule with respect to "determining the payment amount for drugs and biologicals which include intentional overfill." Medicare Programs; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2011, 75 Fed. Reg. 73170, 73466 (Nov. 29, 2010). The final rule definitively concludes, consistent with past policy, that overfill is not included in the ASP calculation and that medical providers may not seek reimbursement for it.

67. Medicare in that regulation clearly states that:

> It has been a long standing Medicare policy that in order to meet the general requirements for coverage under the "incident to" provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies. Such physicians' services and supplies include drugs and biologicals under Section 1861(s)(2)(A) of the Act. In accordance with this policy, provided they only bill for the amount of drug actually purchased and that the cost of the product must represent an expense to the physician.

> We further understand that when a provider purchases a vial or container of product, provider is purchasing an amount of drug defined by the product packaging or label. Any excess product (that is, overfill) is provided without charge to the provider. In accordance with our current policy as explained above, providers may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biological that do not represent a cost to the provider are not reimbursed, and providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.
>
> Because such overfill is currently not included in the calculation of payment limits under the methodology in Section 1847A of the Act and does not represent an incurred cost to the provider, we propose to update our regulations at 42 CFR Part 414 Subpart K to clearly state that the Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We also propose our regulations at Subpart J to clearly state the payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label will not be made under Medicare…

Id. at 73466-67.

68. CMS promulgated upgraded regulations which state that "the manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label." *See* 42 CFR § 414.804(a)(6); further that "CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label," *Id.* 414.904(a)(3)(i); that "additional product contained in the vial or other container does not represent a cost to providers andis not incorporated into the ASP payment limit," *Id.* § 414.904(a)(3)(ii); and that "no payment is made for amounts of product in excess of that reflected on the FDA-approved label," *Id.* § 414.904(a)(3)(iii).

69. These regulations were specifically noted not to be new and substantive changes to previous Medicare policies, but *clarification of existing* CMS policies. Specifically,

CMS noted that "the intent of this proposal is merely to clarify that Medicare ASP payment limit is based on the amount of drug conspicuously indicated on the FDA label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose." 75 Fed. Reg. at 73467. See also *Id.* at 73468 ("the intent of this proposal is to clarify that the ASP payment limit is currently based on the amount of drug indicated on the FDA label, and that no payment will be made for any intentional overfill.") *Id.* at 73468-69 ("the intent of this proposal is to clarify that the ASP payment limit is based on the amount of drug clearly identified as the amount on the FDA label and packaging. We do not intend to change the ASP calculation methodology to include intentional overfill because of the operational difficulty in accurately identifying the amount of the overfill."; *Id.* at 73469 ("our policy clarifies that we will not pay for intentional overfill.") As noted by the regulations above and clarified through the more recent iteration of the CFR's, because CMS deemed overfill "not reimbursable," 75 Fed. Reg. at 73466, it can have no independent value attached to it apart from the rest of the dosage in the vial. The only legitimate purpose of overfill is to ensure that providers and self-administering patients are able to draw up the full dosage amount the FDA recommends that manufacturers include it for this purpose. See 56 Fed. Reg. at 35978.

Manufacturing and Distribution of Injectable Oncology Drugs

How Manufacture and Distribution of Oncology Drug Injections are Supposed to Work per the FDA and CMS Requirements.

70. In the context of the allegations in this Complaint relating to Oncology Drugs, for single use vials, a physician would order a box of Oncology Drugs containing a number of single-use vials depending on how many patients the physician expects to have at

different times needing the Oncology Drugs. The physician would order the Oncology Drugs from a supplier, like Defendant ABDC or Defendant McKesson or one of its Defendant subsidiaries, and Defendant ABDC or Defendant McKesson or one of its Defendant subsidiaries would deliver the product, the Oncology Drugs, to the physician who then stores/refrigerates the Oncology Drugs for use on individual patients as they come in for treatment.

71. By manufacture, design, and regulation, every single-use vial has a standard over-fill in excess of what the vial's label indicates (i.e., the labeled amount) in order to allow for some waste or spillage that can occur when the product is drawn from each vial. *See supra* USP Reference Standards, XXXI Rockfield, MD: (2008 Chapter 1151, page 619).

72. Once the physician has withdrawn the prescribed amount (up to the labeled amount) from the vial, the residue is supposed to be discarded and may not be billed to any government program.

73. Using Oncology Drug Procrit as an example, one box of single-use vials of Procrit contains four 1 ml vials (the concentration can vary between 2K, 3K, 10K, and 40K units, but the vial is always a 1 ml vial). Using the 40K unit vial, which would be labeled as such, each vial contains an over-fill of about 10% above the labeled amount. So instead of having 40K units, the vial actually contains approximately 44K units. When the injection is drawn, 4K units are left over as residue. The residue is supposed to be discarded and may not be billed to any government program. All that the physician can bill is for 40K units and nothing more.

74. Oncology Drugs Aranesp, Neupogen, and Aloxi are only sold in single-use containers (either vials or pre-filled syringes) made by the manufacturer and are sterile.

75. For multi-use vials, a physician would order a box of Oncology Drugs containing a number of multi-use vials which, in the case of Procrit, for example, come in 4 or 6 multi-use vials to the box. Multi-use vials are tapped for draws multiple times either on a given day for multiple patients or over a period of time for multiple draws for use on a single patient.

76. The number of patients needing injections during a particular day or time period will determine how many multi-use vials the physician will need to have available for treatment on that day.

77. Each multi-use vial also has a residue amount to ensure that full dosing is achieved for each injection. Each injection is drawn in accordance with the prescription and labeled amount for the vial. Like single vials, the residue is supposed to be discarded and may not be billed to any government program. The package insert for Procrit specifically states that a needle is NOT to be reinserted into a single dose vial after initial entry.

78. Again, using Procrit as an example, which is manufactured in both single and multi-use vials, the multi-vials come in two different sizes and concentrations: 2 ml that has 20K units total (or 10K units per ml) or 1 ml that has 20K units total (or 20K units per ml). Using the 2 ml multi-use vial as an example, the vial has a label indicating content of 20K units. However, because of the standard 10% over-fill previously described, in reality the vial may contain approximately 22K units. When the injections are drawn, approximately 2K units are left over as residue. The residue is supposed to be discarded and may not be billed to any government program. The physician can bill for 20K units and nothing more.

79. New drugs ("NDAs") are submitted by application to the FDA for approval under 21 U.S.C. §§ 355(b)(1)(D)-(B). These regulations require that the application must include (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacturer, processing, and packing of such drug.

80. Approval by the FDA of the drug formula and method of manufacture is required for the introduction of the drug into interstate commerce and distribution for human use.

81. 21 U.S.C. §§ 314.70 and 314.81 require manufacturers to obtain FDA approval for, or make the FDA aware of, changes in the conditions established in an approved application.

82. The Oncology Drugs must have been manufactured and packaged for distribution and sale by the original manufacturer in accordance with approved FDA standards and have individual expiration dates.

83. The single and multi-use vials of Oncology Drugs supplied by the original manufacturer to Defendant Manufacturer/Distributors have a container closure system which was approved by the FDA as part of the application process to the FDA. The original container closure systems meet and are approved as meeting the stability guidance promulgated by the FDA at 21 CFR §§211.137 and 166.

84. The single and multi-use vial containers, in conformity with FDA requirements and having received FDA approval, are shipped from original manufacturers in sealed containers, marked by lot, containing the number of units per volume, and expiration date, and instructions on storage of the product until it is used for patients, and the use of the product after use for patients.

85. Single use vials are designed and contain the express warning that any excess from the first injection is to be discarded. This is because the Oncology Drug liquid is packed in a sterile container without preservatives.

86. As an example, the single use vial of Oncology Drug Aranesp's package insert clearly states "Aranesp contains no preservatives. Discard any unused portion. Do not pool unused portions from the vials or prefilled syringes. Do not use the vial, prefilled syringe, or autoinjector more than one time…."

87. The package insert for Aranesp clearly warns that Aranesp contains no preservatives and that unused amounts of drug should not be 'pooled' together to make a syringe.

88. Pursuant to U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Guidance for Industry, Changes to an approved NDA or ANDA, April 2004 ("Guidance") CDER must be notified in advance when there is a major change in the drug product including a change in primary packaging components for drug products or for sterile drug products a change to a pre-filled dosage for from another container system.

89. No such advance notice was given by Defendant Manufacturer/Distributors.

The Pre-Filled Syringe Program

90. The Defendant Manufacturer/Distributors have engaged in a deliberate scheme through its self-titled "Pre-Filled Syringe Program" to re-package, re-manufacture, compound, and adulterate the injectable vials and manipulate the ASP in order to increase its profits and increase reimbursement from the Federal, State and City Reimbursement Programs.

91. Defendant Manufacturers/Distributors developed an intentional scheme, through its self-titled "Pre-Filled Syringe Program," under which the FDA approved manufacturing and

packaging requirements and the cGMPs are intentionally altered by Defendant Manufacturer/Distributors. Copies of the various iterations of the agreements are attached as exhibits and referenced as if pled herein.

92. Through its Pre-Filled Syringe Program, Defendant Manufacturers/Distributors removed the Oncology Drug liquid from the single and multiple use vials which had been filled and packaged by the original manufacturer with FDA approval and in accordance with FDA requirements and cGMPs.

93. Defendant Manufacturers/Distributors take the Oncology Drug liquid from the single and multi-dose vials, pool it, and create new re-packaged Pre-filled Syringes, which Defendant Manufacturers/Distributors then sell to provider-physicians through contractual agreements.

94. The Pre-Filled Syringes are given new expiration dates from those on the original single and multi-dose vials packaged by the original manufacturer.

95. As a result of the pooling of the Oncology Drug liquids, Defendant Manufacturers/Distributors use the overfill residue from each of the single and multi-dose vials to create additional Pre-Filled Syringes.

96. Defendant Manufacturers/Distributors do not report the free injections created by the pooling used to create the Pre-Filled Syringes.

97. Because of the pooling, Defendant Manufacturer/Distributor creates a larger quantity of syringes for sale than what existed in the packaging distributed by the original manufacturer because Defendant Manufacturer/Distributor harvests the over-fill for each syringe.

98. Defendant Manufacturer/Distributors contract with provider-physicians to sell the Pre-Filled Syringes and also provides financial incentives to the physicians in the form of discounts and free services to buy their Oncology Drugs in their Pre-Filled Syringe program as opposed to purchasing the Oncology Drugs in the single-dose or multi-dose vials packaged by the original manufacturers and as approved by the FDA for interstate commerce and human use.

Compounding

99. The creation of the Pre-filled Syringes by Defendant Manufacturers/Distributors consists of preparing and packaging a product that is different from that which was created, prepared, packaged, and supplied by the original manufacturer.

100. The Pre-filled Syringes are repackaged, with a new expiration date different than that approved by the FDA, in a different container (the prefilled syringe) without such overfill originally prepared by the manufacturer.

101. The Pre-filled Syringes are not prepared under FDA approved conditions, are not in an FDA approved container, lacking FDA approved stability via a container closure system, and lacking an FDA approved expiration date.

102. By removing the Oncology Drug liquid from the single and multi-use vials, pooling it together, including the over-fill to create the Pre-Filled Syringes, Defendant Manufacturer/Distributors have destroyed the pedigree of the product sold to the provider-physicians, in that a provider/physician cannot determine the source of the injections are required by the Prescription Drug Marketing Act ("PDMA"), 21 U.S.C. 503C(1)(A); FDA Compliance Manual, CPG 160.900.

103. Under the Pre-Filled Syringe program, the pedigrees for the syringes are compromised as the provider/physicians are only provided with the lot from which the pre-filled injections are derived.

104. When ABDC Defendants initiated this scheme in 2001 with the pre-filled syringes, it called it a "compounding program" in its own agreements.

105. McKesson Defendants, for at least Procrit and Aloxi, took the single and multi-use dose vials, as prepared and sold by the manufacturer, and compounded and adulterated them to create new pre-filled syringes, which they then marketed and sold to physicians and other health care providers as pre-filled syringes. These pre-filled syringes were not created under approved FDA guidelines and have been given new expiration dates and altered NDC codes not approved by the FDA.

106. The FDA approved Aloxi for two dosage forms: an oral capsule, which was since discontinued, and single use vials: "ALOXI is supplied as a single-use sterile, clear, colorless solution in glass vials that provides 0.25 mg (free base) per 5 mL."

107. Defendant McKesson's catalogue lists two types of Aloxi for sale (1) a .25 mg (presumably single dose vial); and (2) a .25 mg PF Syringe (PF for pre-filled syringe). *See* attached McKesson Manufacturer Contract Price Changes document, which references both McKesson and OTN. *See also* Packing Slips from McKesson Defendants for the prefilled syringes attached as Exhibits to this Amended Complaint

108. The FDA has not approved the use of Aloxi in a pre-filled syringe.

109. The McKesson Manufacturer Contract Price Changes document from the McKesson PFS Catalogue for Aloxi and Procrit, and also referencing OTN, shows a NDC number for Aloxi in the PF Syringe as 58063-0797-IJ. This document was emailed

to Relator in January 2008. The IJ designation is not an approved NDC number, further evidencing the fact that the pre-filled syringes were created by the McKesson Defendants outside of the FDA approved manufacturing process.

110. The Eisai Reimbursement Code Information Sheet (Eisai purchased MGI Pharma in January 2008), lists two NDC codes for Aloxi neither of which is the NDC code listed by McKesson with an IJ ending. *See* the attached Eisai Reimbursement Codes Information Sheet. This same document does not indicate that Eisai sells a pre-filled syringe.

111. The same is true for Procrit. McKesson and OTN advertise selling Procrit in a 40,000 U/ML PF Syringe (pre-filled). *See* McKesson PFS Catalogue. Yet, the FDA has only approved Procrit in single or multi use vials. There is no FDA approval for a pre-filled syringe of Procrit.

112. McKesson Defendants sent invoices to customers, including Relator, some of which are captioned specifically for pre-filled syringes and others which list Aloxi sales of .05mg/ml syringes, a dose and packaging not approved by the FDA.

113. Additionally, the Procrit being sold by McKesson Defendants as listed on the McKesson PFS Catalogue includes an NDC code with an "IJ" ending, not the NDC code on record with the FDA.

114. Compounding in and of itself is not unlawful, but compounding becomes unlawful, where, as here, the compounded drugs are billed improperly and where it is a cover-up for manufacturing and distributing unapproved drugs. *See FDA Compliance Guidance, CPG 460.200.*

115. Furthermore, Defendants are not preparing these syringes on a patient specific basis. Relator has specific knowledge from ordering prefilled syringes in the past that orders can be placed up to 6 pm for delivery the next day. With the time necessary to deliver the product to Fedex for overnight delivery from Dothan, Alabama, there would be no time to manufacture the syringes and get them shipped if they were truly patient specific. The only realistic explanation is that Defendants are manufacturing these syringes throughout the day and merely fulfilling orders when received by providers.

Adulteration

116. Drugs are deemed to be adulterated if they are not manufactured in compliance with the cGMAs or if they are contaminated. *See 21 USC §351 (a)(2)(A)(B).*

117. As explained above, the Pre-Filled Syringes are not manufactured in compliance with cGMAs and pose a significant safety risk of infection.

118. By pooling the Oncology Drug liquid from the single and multi-use vials, including the overfill, and using it collectively to create Pre-Filled Syringes, Defendant Manufacturer/Distributor is creating and selling adulterated and compounded drugs, which may not be sold in commerce and which are not reimbursable by any governmental or private insurance company. This would apply to the all products sold by Defendants under the pre-filled syringe program, whether from the overfill or not.

Manufacturing

119. FDA guidance CPG 460.200 states that "[p]harmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Food, Drug and Cosmetic Act as manufacturers."

120. Defendant Manufacturer/Distributors through its Pre-Filled Syringe Program, and the above described actions, have engaged the manufacturing and distributing drugs for human use and placed its Pre-Filled Syringes into commerce and for human use without FDA approval.

121. Defendant Manufacturer/Distributors have not complied with the same provisions of the FDA Act applicable to manufacturers and thus its Pre-Filled Syringes are not legally being manufactured or sold in commerce and are not reimbursable by any governmental or private insurance company.

Unlawful Profiting from the Sale of the Pre-Filled Syringes and Improper Manipulation of the ASP

122. CMS determines the reimbursement rate for injectables based on each billing code and using a weighted average sales price calculated with Average Sales Price ("ASP") data submitted by manufacturers.

123. Manufacturers submit ASP data at the 11-digit National Drug Code (NDC) level by submitting the number of units of the 11-digit NDC sold and the ASP for those units.

124. The number of billing units in an NDC is determined by the amount of drug in the package. For example: a manufacturer sells a box of 4 vials of a drug. Each vial contains 20 milligrams (mg). The billing code is per 10 mg. The number of billing units in this NDC for this billing code is (4 vials X 20 mg)/10 mg=8 billable units.

125. Beginning April 1, 2008, CMS began using a new weighting methodology to determine the payment limit. CMS sums the product of the manufacturer's ASP and the

number of units of the 11-digit NDC sold for each NDC assigned to the billing and payment code, and then divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code. CMS weighs the ASP for an NDC by the number of billing units sold for that NDC.

126. Prior to April 1, 2008, CMS converted the manufacturer's ASP for each NDC into the average sales price per billing unit by dividing the manufacturer's ASP for that NDC by the number of billing units in that NDC. CMS would sum the product of the ASP per billing unit and the number of units of the 11-digit NDC sold for each NDC assigned to the billing code, and then divide this total by the sum of the number of units of the 11-digit NDC sold for each NDC assigned to the billing code. CMS weighted the ASP per billing units equally for each NDC regardless of package size.

127. Defendant Manufacturer/Distributors have skewed the ASP process by introducing product into commerce specifically excluded from the calculation of ASP. As such, the injections manufactured by Defendants are reimbursed at a rate set by CMS through the reported data from the original manufacturer, which yields a reimbursement rate that is higher per dose because these pre-filled injections created by Defendants were never calculated in setting the price, causing damage to the Government.

128. This allows Defendants to sell these adulterated injections downstream from the data reporting used by CMS to set reimbursement, and therefore CMS and government payment programs are paying for more injections than were originally represented to CMS as being in commerce. As such the reimbursement rate is artificially higher than it

should be and to the detriment to the Medicare and Medicaid programs and the Federal and State, and City governments.

129. Defendant Manufacturer/Distributor intentionally initiated and promulgated the Pre-Filled Syringe Program to place into commerce adulterated injections created in whole or in part from harvested overfill from vials of drugs, and to cause false claims to be submitted to the Federal, State and City reimbursement programs.

130. The agreements attached as exhibits to this complaint and incorporated as if pled herein specifically state that overfill is to be used by Defendants for resale in commerce. However Defendants neither sought FDA approval for these drugs nor reported data as a manufacturer to CMS for ASP purposes.

131. When a provider orders a pre-filled syringe manufactured by Defendants Manufacturer/Distributors under the prefilled syringe program, he/she has no ability to determine the sterility, pedigree, or source of the syringe as it may have been made from one vial or multiple vials harvested for their overfill. Relator has ordered Aloxi in both prefilled syringes as well as single dose vials.

132. In fact Defendants conceal the nature of these drugs from providers on both the invoice and the pedigree. The invoice for a single dose vial and a prefilled syringe both states that the '"specific Unit" was obtained "directly" from the manufacturer (see attached invoices)[1], while the pedigree for the prefilled syringe is no different than that of the single dose vial prepared by the manufacturer. The attached pedigree from 2/28/2007 is for a prefilled syringe which is no different than that of the pedigree provided to Relator for a single dose vial, an example of which is attached from 9/2/2008.

[1] Defendants routinely use abbreviations on their documents to identify what type of drug is purchased. "SDV" stands for Single Dose Vial. "FOR PF" stands for PreFilled Syringe. "MDV" stands for MultiDose Vial.

133. This presents an infection risk to patients already at a higher risk for infections given their disease state. Should the source of an infection be from a prefilled syringe manufactured by defendants, there would be no way to tell from which vial the adulterated material came from.

134. As defined under 31 U.S.C. §3729(b), "knowing" and "knowingly" mean: (1) actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or, (3) acts in reckless disregard of the truth or falsity of the information.

135. Although Defendant Manufacturer/Distributors did not themselves submit claims for reimbursement to the Government, they knowingly caused false claims to be presented to the Government when, among other things, they (1) unlawfully promoted distributed and sold "Pre-Filled Syringes" to provider physicians which were not approved by the FDA and were not in compliance with cGMPs, which Defendant Manufacturer/Distributors knew would be submitted for reimbursement by provider physicians to the Government; (2) made misrepresentations of fact which affected the ASP and reimbursement of the Oncology Drugs; and (3) provided financial inducements designed to persuade Provider/Physicians to participate in the scheme.

COUNT 1
Federal False Claims Act-Presentation of False Claim-31 U.S.C. § 3729(a)(1)

136. Relator re-alleges and incorporates paragraphs 1-135 of this Complaint as if fully set forth herein.

137. This is a claim for penalties and treble damages under the Federal False Claims Act.

138. In performing the acts described above, Defendants Manufacturers/Distributors, through the acts of their officers, agents, employees and sales representatives for the purpose of defrauding the Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Medicare, Medicaid and other Government health programs to officers, employees or agents of the United States Government, within the meaning of 31 U.S.C. § 3729(a)(1).

139. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

140. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

141. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

COUNT 2
Federal False Claims Act-False Statements-31 U.S.C. § 3729(a)(2)

142. Relator re-alleges and incorporates paragraphs 1-135 of this Complaint as is fully set forth herein.

143. In performing the acts described above, Defendants Manufacturers/Distributors through the acts of their officers, agents, employees and sales representatives knowingly made, used, or caused to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the Government in violation of 31 U.S.C §3729(a)(2).

144. The United States, unaware of the foregoing circumstances and conduct of the Defendants Manufacturer/Distributors, made full payments which resulted in its being damages in an amount to be determined.

145. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim paid or approved arising from the Defendants Manufacturer/Distributors' fraudulent conduct as described herein.

COUNT 3
Payment Under Mistake of Fact

146. Relator re-alleges and incorporates paragraphs 1-135 of the Complaint as if fully set forth herein.

147. This is an action to recover monies paid by the United States and the States and Cities under a mistake of fact that was caused by Defendants Manufacturers/Distributors through the activities described in the Complaint.

148. The United States and the States and Cities made payments for Pre-Filled Syringes under the erroneous belief that the records, statements, and proposed amount upon which reimbursement was based were true, correct and proper.

149. The United States and the States' erroneous beliefs were material to the payments made by the States, Cities and Federal Government.

150. Because of these mistakes of fact, the United States and States and Cities paid moneys for the Pre-Filled Syringes that were not properly reimbursable and to which the United States and the States and Cities are entitled.

151. By reason of these payments, the United States and the States and Cities have suffered damages in an amount to be determined.

COUNT 4

Unjust Enrichment

152. Relator re-alleges and incorporates paragraphs 1-135 of the Complaint as if fully set forth herein.

153. This is an action to recover monies by which Defendants Manufacturer/ Distributors have been unjustly enriched. Due to the Defendants Manufacturer/ Distributors improper practices, the United States and the States and Cities paid monies by which Defendants have been unjustly enriched.

154. By reason of their payments, the United States and the States and Cities are entitled to damages in an amount to be determined.

COUNT 5
(California False Claims Act-Cal. Gov't Code § 12651(a)(1))

133. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

134. This is a claim for penalties and treble damages for violation of the California False Claims Act.

135. By virtue of the acts described above, Defendants Manufacturers/Distributors, for the purpose of defrauding the California State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other California State funded programs to officers or employees of the state within the meaning of Cal. Gov't Code § 12651(a)(1).

136. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the California State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid

and other California State funded programs within the meaning of Cal. Gov't Code § 12651(a)(2).

137. As a result, California State monies were lost through payments made in respect of the claims and other costs were sustained by the California State Government.

138. Therefore, the California State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

139. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein. or approved arising from the Defendants' fraudulent conduct as described herein.

COUNT 6

(Colorado Medicaid False Claims Act C.R.S.A. §25.5-4-300.4 *et seq)*

140. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

141. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

142. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Colorado State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Colorado State funded programs within the meaning of C.R.S.A §25.5-4-304.

143. As a result, Colorado State monies were lost through payments made in respect of the claims and other costs were sustained by the Colorado State Government.

144. Therefore, the Colorado State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

145. Additionally, the Colorado State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein as well as costs as permitted under the statute.

COUNT 7

(Connecticut False Claims Act –C.G.S.A. §17b-301 et seq)

146. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

147. This is a claim for penalties and treble damages under the Connecticut False Claims Act.

148. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Connecticut State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Connecticut State funded programs within the meaning of C.G.S.A §17b-301(a) and 301(b).

149. As a result, Connecticut State monies were lost through payments made in respect of the claims and other costs were sustained by the Connecticut State Government.

150. Therefore, the Connecticut State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

151. Additionally, the Connecticut State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein as well as costs as permitted under the statute.

COUNT 8

(Delaware False Claims and Reporting Act- 6 Del. C. § 1201 et seq)

152. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

153. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

154. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly presented and/or caused to be presented, directly or indirectly, false or fraudulent claims for payment or approval under Medicaid and other Delaware State funded programs to officers or employees of the state within the meaning of 6 Del. C. § 1201(a)(1)

155. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Delaware State Government, knowingly made, used, and/or caused to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Delaware State funded programs within the meaning of 6 Del. C. § 1201(a)(2).

156. As a result, Delaware State monies were lost through payments made in respect of the claims and other costs were sustained by the Delaware State Government.

157. Therefore, the Delaware State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted under the statute.

158. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim presented and caused to be presented by

Defendant Manufacturer/Distributor and arising from their fraudulent conduct as described herein.

COUNT 9

(District of Columbia Procurement Reform Amendment Act-D.C. Code § 2-308 et seq)

159. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

160. This is a claim for penalties and treble damages under the District of Columbia Procurement Reform Amendment Act.

161. By virtue of the acts described above, Defendant Manufacturer/Distributor, for the purpose of defrauding the District of Columbia Government, knowingly presented and/or caused to be presented, false claims for payment or approval under Medicaid and other District of Columbia funded programs to officers or employees of the District within the meaning of D.C. Code § 2-308.14(a)(1).

162. By virtue of the acts described above, Defendant Manufacturer/Distributor, for the purpose of defrauding the District of Columbia Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other District of Columbia funded programs within the meaning of D.C. Code § 2-308.14(a)(2).

163. As a result, District of Columbia monies were lost through payments made in respect of the claims and other costs were sustained by the District of Columbia Government.

164. Therefore, the District of Columbia Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

165. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributor and arising from their fraudulent conduct as described herein.

COUNT 10
(Florida False Claims Act-Fla. Stat. § 68.082 et seq)

166. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

167. This is a claim for penalties and treble damages under the Florida False Claims Act.

168. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Florida State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Florida State funded programs to officers or employees of the state within the meaning of Fla. Stat. § 68.082(2)(a).

This is a claim for penalties and treble damages under the Florida False Claims Act.

169. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Florida State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Florida State funded programs within the meaning of Fla. Stat. § 68.082(2)(b).

170. As a result, Florida State monies were lost through payments made in respect of the claims and other costs were sustained by the Florida State Government.

171. Therefore, the Florida State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

172. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer Distributors and arising from their fraudulent conduct as described herein.

COUNT 11
(Georgia State False Medicaid Claims Act-Ga. Code Ann. § 49-4-168 et seq)

173. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

174. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

175. By virtue of the acts described above, Defendants Manufacturer/Distributors, for the purpose of defrauding the Georgia State Government, knowingly presented and/or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval within the meaning of Ga. Code Ann. § 49-4-168.1(a)(1).

176. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Georgia State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program within the meaning of Ga. Code Ann. § 49-4-168.1(a)(2).

177. As a result, Georgia State monies were lost through payments made in respect of the claims and other costs were sustained by the Georgia State Government.

178. Therefore, the Georgia State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

179. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented or caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

COUNT 12
(Hawaii False Claims Act- Haw. Rev. Stat. § 661-21 et seq)

180. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

181. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

182. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Hawaii State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Hawaii State funded programs to officers or employees of the state within the meaning of Haw. Rev. Stat. § 661-21(a)(1).

183. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Hawaii State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Hawaii State funded programs within the meaning of Haw.Rev. Stat. § 661-21)(a)(2).

184. As a result, Hawaii State monies were lost through payments made in respect of the claims and other costs were sustained by the Hawaii State Government.

185. Therefore, the Hawaii State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

186. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

COUNT 13
(Illinois Whistleblower Reward and Protection Act-740 Ill. Comp. Stat. 175/3 et seq)

187. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

188. This is a claim for penalties and treble damages under the Illinois Whistleblower Reward and Protection Act.

189. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Illinois State funded programs to officers or employees of the state within the meaning of 740 Ill. Comp. Stat. 175/3(a)(1).

190. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Illinois State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Illinois State funded programs within the meaning of 740 Ill. Comp. Stat. 175/3(a)(2).

191. As a result, Illinois State monies were lost through payments made in respect of the claims and other costs were sustained by the Illinois State Government.

192. Therefore, the Illinois State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

193. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

Count 14
(Indiana False Claims and Whistleblower Protection Act Ind. Code § 5-11-5.5-2 et seq)

194. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

195. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

196. By virtue of the acts described above, Defendant Manufacturer/ Distributors, for the purpose of defrauding the Indiana State Government, knowingly or intentionally presented and/or caused or induced another to present false claims under Medicaid and other Indiana State funded programs to the state for payment or approval within the meaning of Ind. Code § 5-11-5.5-2(b)(1) and (8).

197. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Indiana State Government, knowingly or intentionally made, used, and/or caused or induced another to make or use, false records or statements to obtain payment or approval of a false claim under Medicaid and other Indiana State funded programs within the meaning of Ind. Code § 5-11-5.5-2(b)(2) and (8).

198. As a result, Indiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Indiana State Government.

199. Therefore, the Indiana State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

200. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from the Defendant Manufacturer/Distributors' fraudulent conduct as describe herein.

Count 15
(Iowa False Claims Act- I.C.A. §685.2 et seq)

201. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

202. This is a claim for penalties and treble damages under the Iowa False Claims Act.

203. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Iowa State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Iowa State fund, Iowa State monies were lost through payments made in respect of the claims and other costs were sustained by the Iowa State Government.

204. Therefore, the Colorado State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

205. Additionally, the Colorado State Government is entitled to the maximum penalty of $10,000 and for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein as well as costs as permitted under the statute.

Count 16

(Louisiana Medical Assistance Programs Integrity Law La. Rev. Stat. 46:438.3(A) and (B))

206. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

207. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

208. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Louisiana State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Louisiana State funded programs within the meaning of La. Rev. Stat. 46:438.3(A).

By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Louisiana State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of La. Rev. Stat. 46:483.3(B).

209. As a result, Louisiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Louisiana State Government.

210. Therefore, the Louisiana State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

211. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. 46:438.6(B)(2).

Count 17
(Maryland False Claims Act- Md. Code Health General §2-601 et seq)

212. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

213. This is a claim for a fine and damages under the Maryland False Claims Act.

214. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Maryland State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of Md. Code Health General §2-601-602).

215. As a result, Maryland State monies were lost through payments made in respect of the defendants' conduct and other costs were sustained by the Maryland State Government.

216. Therefore, the Maryland State Government has been damaged in an amount to be proven at trial.

217. Additionally, the Maryland State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. Md. Code Health General §2-602).

Count 18

(Massachusetts False Claims Act- Mass. Gen. L. Ch. 12, §§ 5B(2))

218. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

219. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

220. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth within the meaning of Mass. Gen. L. Ch. 12, §§ 5B(2).

221. As a result, Massachusetts Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Massachusetts Commonwealth Government.

222. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

223. Additionally, the Massachusetts Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

Count 19

(Michigan Medicaid False Claims Act Mich. Comp. Laws § 400.601 et seq)

224. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

225. This is a claim for damages and a civil penalty under the Michigan Medicaid False Claims Act.

226. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Michigan State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Michigan a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the State, knowing the claim to be false within the meaning of Mich. Comp. Law §§ 400.601 *et seq*.

227. As a result, Michigan State monies were lost through payments made in respect of the claims and other costs were sustained by the Michigan State Government.

228. Therefore, the Michigan State Government has been damaged in an amount to be proven at trial.

229. Additionally, the Michigan State Government is entitled to a civil penalty equal to the full amount of the benefit received by the Defendant Manufacturer/Distributors plus triple the amount of damages suffered by the state as a result of the conduct by Defendant Manufacturer/Distributors as described herein.

Count 20

(Minnesota False Claims Act Minn. Stat. §15C.01 et seq)

230. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

231. This is a claim for penalties and treble damages under the Miinesota False Claims Act.

232. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Minnesota Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Minnesota Government within the meaning of Minn. Stat §15C.01.

233. As a result, Minnesota State monies were lost through payments made in respect of the claims and other costs were sustained by the Minnesota Government.

234. Therefore, the Minnesota Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

235. Additionally, the Minnesota Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein as well.

236. Additionally, the Minnesota Government is entitled to a civil penalty equal to the full amount of the benefit received by the Defendant Manufacturer/Distributors plus triple the amount of damages suffered by the state as a result of the conduct by Defendant Manufacturer/Distributors as described herein.

Count 21

(Montana False Claims Act- M.C.A. §17-8-401 et seq)

237. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

238. This is a claim for damages and a civil penalty under the Montana Medicaid False Claims Act.

239. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the

purpose of defrauding the Montana State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Montana a claim knowing the claim to be false within the meaning of M.C.A. § 17-8-402.

240. As a result, Montana State monies were lost through payments made in respect of the claims and other costs were sustained by the Montana State Government.

241. Therefore, the Montana State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

242. Additionally, the Montana State Government is entitled to a civil penalty equal to the full amount of the benefit received by the Defendant Manufacturer/Distributors plus triple the amount of damages suffered by the state as a result of the conduct by Defendant Manufacturer/Distributors as described herein.

Count 22

(Nevada False Claims Act Nev. Rev. Stat. § 357.040(1)(a))

243. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

244. This is a claim for penalties and treble damages under the Nevada False Claims Act, entitled "Submission of False Claims to State or Local Government."

245. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Nevada State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Nevada State funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(a).

246. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly made, used, and/or caused to be made or used, false

records or statements to get false claims paid or approved under Medicaid and other Nevada State funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(b).

247. As a result, Nevada State monies were lost through payments made in respect of the claims and other costs were sustained by the Nevada State Government.

248. Therefore, the Nevada State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

249. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/ Distributors and arising from their fraudulent conduct as described herein.

Count 23

(New Hampshire False Claims Act N.H. Rev. Stat. Ann. § 167:61-b(I)(a)- (b))

250. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

251. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

252. By virtue of the acts described above, Defendant Manufacturer/ Distributors, for the purpose of defrauding the New Hampshire State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New Hampshire State funded programs to officers or employees of the state within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(a).

253. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New Hampshire State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under

Medicaid and other New Hampshire State funded programs within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(b).

254. As a result, New Hampshire state monies were lost through payments made in respect of the claims and other costs were sustained by the New Hampshire State Government.

255. Therefore, the New Hampshire State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

256. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

Count 24

(New Jersey False Claims Act- N.J.S.A. 2A:32C-1 et seq)

257. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

258. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

259. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New Jersey State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State funded programs to the State within the meaning of N.J.S.A. 2A:32C-2).

260. As a result, New Jersey State monies were lost through payments made in respect of the claims and other costs were sustained by the New Jersey State Government.

261. Therefore, the New Jersey State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

262. Additionally, the New Jersey State Government is entitled to the maximum penalty under N.J.S.A. 2A:32C-3 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

Count 25

(New Mexico Medicaid False Claims Act N.M. Stat. Ann. § 27-14-4 et seq)

263. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

264. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

265. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New Mexico State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State funded programs to the State within the meaning of N.M. Stat. Ann. § 27-14-4(A).

266. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New Mexico State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Mexico State funded programs within the meaning of N.M. Stat. Ann. § 27-14-4(C).

267. As a result, New Mexico State monies were lost through payments made in respect of the claims and other costs were sustained by the New Mexico State Government.

268. Therefore, the New Mexico State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

269. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

Count 26

(New York False Claims Act N.Y. State Fin. Law § 189(1)(a)-(b))

270. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

271. This is a claim for penalties and treble damages under the New York False Claims Act.

272. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New York State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York State funded programs to officers or employees or agents of the state within the meaning of N.Y. State Fin. Law § 189(1)(a).

273. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New York State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York State funded programs within the meaning of N.Y. State Fin. Law § 189(1)(b).

274. As a result, New York State monies were lost through payments made in respect of the claims and other costs were sustained by the New York State Government.

275. Therefore, the New York State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

276. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

Count 27

(North Carolina False Claims Act- N.C.G.S.A. § 1-605 et seq.)

277. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

278. This is a claim for penalties and treble damages under the North Carolina False Claims Act.

279. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the North Carolina State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other North Carolina State funded programs to officers or employees of the state within the meaning of N.C.G.S.A. § 1-606.

280. As a result, North Carolina State monies were lost through payments made in respect of the claims and other costs were sustained by the North Carolina State Government.

281. Therefore, the North Carolina State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

282. Additionally, the North Carolina State Government is entitled to the maximum penalty of $11,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/ Distributors and arising from their fraudulent conduct as described herein.

Count 28

(Oklahoma Medicaid Program Integrity Act- 56 Okl. St. Ann. §1001 et seq)

283. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

284. This is a claim for penalties and treble damages under the Oklahoma False Claims Act.

285. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Oklahoma State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Oklahoma State funded programs to officers or employees of the state within the meaning of 56 Okl. St. Ann. §1005.

286. As a result, Oklahoma State monies were lost through payments made in respect of the claims and other costs were sustained by the Oklahoma State Government.

287. Therefore, the Oklahoma State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

288. Additionally, the Oklahoma State Government is entitled under 56 Okl. St. Ann. §1006 to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/ Distributors and arising from their fraudulent conduct as described herein.

Count 29

(Rhode Island State False Claims Act- Gen. Laws 1956, § 9-1.1-1)

289. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

290. This is a claim for penalties and treble damages under the State False Claims Act.

291. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Rhode Island State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Rhode Island State funded programs to officers or employees of the state within the meaning of Gen. Laws 1956, § 9-1.1-3.

292. As a result, Rhode Island State monies were lost through payments made in respect of the claims and other costs were sustained by the Rhode Island State Government.

293. Therefore, the Rhode Island State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

294. Additionally, the Rhode Island State Government is entitled under Gen. Laws 1956, § 9-1.1-3 to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/ Distributors and arising from their fraudulent conduct as described herein.

Count 30

(Tennessee False Claims Act- Tenn. Code Ann. § 4-18-103(a)(1)-(2))

295. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

296. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

297. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Tennessee State funded programs to officers or employees of the state within the meaning of Tenn. Code Ann. § 4-18-103(a)(1).

298. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Tennessee State funded programs within the meaning of Tenn. Code Ann. § 4-18-03(a)(2).

299. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

300. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

301. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/ Distributors and arising from their fraudulent conduct as described herein.

Count 31

(Tennessee Medicaid False Claims Act Tenn. Code Ann. § 71-5-182(a)(1)(A)-(B))

302. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

303. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

304. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented to the state claims for payment under the Medicaid program knowing such claims were false or fraudulent within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(A).

305. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the state knowing such record or statement were false within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(B).

306. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

307. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

308. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendant Manufacturer/Distributors' fraudulent conduct as described herein.

Count 32

(Texas Medicaid Fraud Prevention Law Tex. Hum. Res. Code § 36.002 et seq)

309. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

310. This is a claim for restitution, interest, penalties and double damages under the Medicaid Fraud Prevention Law.

311. By virtue of the acts described above, the Defendant Manufacturer/Distributors, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, and/or caused to be made, false statements or representations of material facts on applications for contracts, benefits, or payments under the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(1)(A).

312. By virtue of the acts described above, the Defendant Manufacturer/Distributors, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, caused to be made, induced, and/or sought to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(4)(B).

313. As a result, Texas State monies were lost through payments made in respect of the false statements or representations and other costs were sustained by the Texas State Government.

314. Therefore, the Texas State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

315. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by the Defendant Manufacturer/Distributors under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

Count 33

(Virginia Fraud Against Taxpayers Act Va. Code Ann. § 8.01-216.3(A)(1)-(2))

316. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

317. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

318. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Virginia Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and

other Virginia Commonwealth funded programs to officers or employees of the Commonwealth within the meaning of Va. Code Ann. § 8.01-216.3(A)(1).

319. By virtue of the acts described above, Defendant Manufacturer/ Distributors, for the purpose of defrauding the Virginia Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth under Medicaid and other Virginia Commonwealth funded programs within the meaning of Va. Code Ann. § 8.01-216.3(A)(2).

320. As a result, Virginia Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Virginia Commonwealth Government.

321. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

322. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

Count 34

(Wisconsin Medical Assistance False Claims Act -W.S.A. 49.485; 49.49)

323. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

324. This is a claim for penalties and treble damages under the Wisconsin Medical Assistance False Claims Act.

325. By virtue of the acts described above, Defendant Manufacturer/ Distributors, for the purpose of defrauding the Wisconsin Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid

or approved by the State under Medicaid and other Wisconsin State funded programs within the meaning of W.S.A. 49.485; 49.49.

326. As a result, Wisconsin State monies were lost through payments made in respect of the claims and other costs were sustained by the Wisconsin State Government.

327. Therefore, the Wisconsin State Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

328. Additionally, the Wisconsin State Government is entitled under to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendant Manufacturer/Distributors' fraudulent conduct as described herein.

Count 35

(Chicago False Claims Act Chicago Mun. Code Ch. 1-22-020(1)-(2))

329. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

330. This is a claim for penalties and treble damages under the Chicago False Claims Act.

331. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Chicago City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Chicago City funded programs to officers or employees of the City within the meaning of Chicago Mun. Code Ch. 1-22-020(1).

332. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the Chicago City Government, knowingly made, used, and/or caused to be made or used, false records or statement to get false claims paid or approved under Medicaid and other Chicago City funded programs within the meaning of Chicago Mun. Code ch. 1-22-020(2).

333. As a result, Chicago City monies were lost through payments made in respect of the claims and other costs were sustained by the Chicago City Government.

334. Therefore, the Chicago City Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

335. Additionally, the Chicago City Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

Count 36

(New York City False Claims Act NYC Admin. Code § 7-803(a)(1))

336. Relator re-alleges and incorporates paragraphs 1 – 135 of the Complaint as if fully set forth herein.

337. This is a claim for penalties and treble damages under the New York City False Claims Act.

338. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New York City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York City funded programs to officers or employees of the City within the meaning of NYC Admin. Code § 7-803(a)(1).

339. By virtue of the acts described above, Defendant Manufacturer/Distributors, for the purpose of defrauding the New York City Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York City funded programs within the meaning of NYC Admin. Code § 7-803(a)(2).

340. As a result, New York City monies were lost through payments made in respect of the claims and other costs were sustained by the New York City Government.

341. Therefore, the New York City Government has been damaged in an amount to be proven at trial and is entitled to treble damages as permitted by statute.

342. Additionally, the New York City Government is entitled to the maximum penalty of $15,000 for each and every false claim presented and caused to be presented by Defendant Manufacturer/Distributors and arising from their fraudulent conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for the following relief:

A. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the United States, plus a civil penalty of up to $11,000 for each violation of 31 U.S.C. § 3729 proven at trial;

B. Judgment in amount of proven damages at trial for payment in mistake of fact and unjust enrichment;

C. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of California, plus a civil penalty of $10,000 for each violation of Cal. Gov't Code § 12651 proven at trial;

D. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Colorado, plus a penalty of $10,000 for each violation of the Colorado False Claims Act, C.R.S.A §25.5-4-304, as well as costs as permitted under the statute.

E. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Connecticut, plus a penalty of $10,000 for each violation of the Connecticut State funded programs within the meaning of C.G.S.A §17b-301(a) and 301(b), as well as costs as permitted under the statute.

F. Judgment in an amount equal to treble damages to be proven at trial against Defendants and in favor of the State of Delaware, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201 proven at trial;

G. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the District of Columbia, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14 proven at trial;

H. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Florida, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082 proven at trial;

I. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Georgia, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. § 49-4-168.1 proven at trial;

J. Judgment in an amount equal to treble the damages to be proven at trial againstDefendants and in favor of the State of Hawaii, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21 proven at trial.

K. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Illinois, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3 proven at trial;

L. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Indiana, plus a civil penalty of at least $5,000 for each violation of Ind. Code § 5-11-5.5-2(b) proven at trial;

M. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Iowa, plus a civil penalty of at least $10,000 for

each violation of the Iowa False Claims Act proven at trial as well as costs as permitted by statute.

N. Judgment in an amount equal to the damages to be proven at trial against Defendants and in favor of the State of Louisiana, plus a civil fine in the amount of three times the amount of actual damages sustained for each violation of La. Rev. Stat. 46:438.3 proven at trial.

O. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Maryland;

P. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the Commonwealth of Massachusetts, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12, § 5B proven at trial;

Q. Judgment in an amount equal to the damages to be proven at trial against Defendants and in favor of the State of Michigan, plus a civil penalty equal to the full amount of the benefit received by the Defendants plus triple the amount of damages suffered by the state for each violation of Mich. Comp. Laws § 400.610a proven at trial;

R. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Minnesota, plus a civil penalty of $10,000 for each violation of Minn. Stat §15C.01proven at trial;

S. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Montana;

T. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Nevada, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §§ 357.040 proven at trial;

U. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of New Hampshire, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I) proven at trial;

V. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of New Jersey, plus a civil penalty of $10,000 for each violation of N.J.S.A. 2A:32C-2proven at trial;

W. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of New Mexico, plus a civil penalty for each violation of N.M. Stat. Ann. § 27-14-4 proven at trial;

X. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of New York, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. Law § 189 proven at trial;

Y. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of North Carolina, plus a civil penalty of $11,000 for each violation of N.C.G.S.A. § 1-606 proven at trial.

Z. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Oklahoma, plus a civil penalty of $10,000 for each violation proven at trial pursuant to 56 Okl. St. Ann. §1006;

AA. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Oklahoma, plus a civil penalty of $10,000 for each violation proven at trial pursuant Gen. Laws 1956, § 9-1.1-3;

BB. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § Tenn. Code Ann. § 4-18-103 proven at trial;

CC. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182 proven at trial;

DD. Judgment in an amount equal to restitution, interest, and two times the damages to be proven at trial against Defendants and in favor of the State of Texas, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §§ 36.002 proven at trial;

EE. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the Commonwealth of Virginia, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3 proven at trial;

FF. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Wisconsin plus a civil penalty of $10,000 for each violation proven at trial pursuant W.S.A. 49.485; 49.49;

GG. Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the City of Chicago, plus a civil penalty of $10,000 for each violation of Chicago Mun. Code ch. 1-22-020 proven at trial;

HH. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the City of New York, plus a civil penalty of $15,000 for each violation of NYC Admin. Code § 7-803 proven at trial;

II. An award to Relator of the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and equivalent provisions in the state statutes set forth above, including the costs and expenses of this action and reasonable attorneys' fees;

JJ. All such other, further and different relief, whether preliminary or permanent, legal, general or equitable, as the Court deems just and proper.

JURY DEMAND

KK. Relator hereby demands a trial by Jury in this matter.

Respectfully submitted,

By: _____

J. Marc Vezina
VEZINA AND GATTUSO, L.L.C.
LA Bar No. 24683
TX Bar No 24000141
GA Bar No. 465449
MI Bar No. P76232
401 Weyer Street, P. O. Box 461
Gretna, LA 70054
jmv@vezinagattuso.com
Tel. (504) 368-5223
Cell: (504) 813-6100
Fax (504) 361-3624

Attorney for Relator Omni Healthcare, Inc.

By: s/Monica P. Navarro
Monica P. Navarro (Michigan P52985)
Special Counsel to Vezina and Gattuso, L.L.C.
401 Weyer Street, P. O. Box 461
Gretna, LA 70054
Tel. (248) 390-2323

Attorney for Relator Omni Healthcare, Inc.

By: s/Michelle Bayer
Michelle Bayer (Michigan P55546)
Michelle Bayer PLC
Of Counsel to Vezina Gattuso
4190 Telegraph Rd., Ste 3300
Bloomfield Hills, Michigan 48322
mbayer@mbayerlaw.com
Tel. (248) 568-5714
Fax (248)644-2801

Attorneys for Relator Omni Healthcare, Inc.